



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0860]

Glen R. Justice: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Glen R. Justice, M.D. from providing services in any capacity to a person that has an approved or pending drug product application for a period of 25 years. We base this order on a finding that Dr. Justice was convicted of five felony counts under Federal law for conduct involving health care fraud and that this pattern of conduct was sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. Dr. Justice was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Justice failed to respond. Dr. Justice's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade,
Office of Regulatory Affairs,
Food and Drug Administration,
12420 Parklawn Dr.,
Rockville, MD 20857,
301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of any criminal offense, and it finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

On July 25, 2011, the U.S. District Court for the Central District of California entered judgment against Dr. Justice for health care fraud in violation of 18 U.S.C. 1347, and aiding and abetting and causing an act to be done in violation of 18 U.S.C. 2.

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for this conviction is as follows: Dr. Justice was a physician licensed by the State of California. Dr. Justice owned and operated a medical practice in the

Central District of California and he enrolled as a provider with federally-funded and private health care programs.

Dr. Justice devised and executed a scheme to defraud federally-funded and private health care benefit programs. As part of the scheme, Dr. Justice knowingly and willfully submitted, and caused to be submitted, false and fraudulent claims to health care benefit programs for injectable medications, knowing that those medications were never provided to the patients and he billed patients health care benefit programs for more expensive injectable medications when less expensive medications were provided. Dr. Justice continued his conduct despite being advised by staff to desist and subsequent to the execution of a search warrant at his medical practice in 2006. As a result of Dr. Justice's fraudulent business practices, health care benefit programs suffered losses between \$400,000 and \$1,000,000.

As a result of his convictions, on March 26, 2012, FDA sent Dr. Justice a notice by certified mail proposing to debar him for 25 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, that Dr. Justice was convicted of felonies under Federal law for conduct which involved health care fraud, and that the Agency found, on the basis of the conviction and other information, that Dr. Justice had demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. This conclusion was based on the fact that Dr. Justice had legal and professional obligations to ensure that he submitted accurate medical claims for procedures he performed, as well as administering medicines that were appropriate for his patients' condition, which he knowingly and willingly disregarded, as well as the fact that Dr. Justice intentionally billed for different FDA- regulated drug products than what he wrote

prescriptions for. Therefore, FDA had reason to believe that, if Dr. Justice were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. The proposal offered Dr. Justice an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 29, 2012. Dr. Justice failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Glen R. Justice has been convicted of five counts of a felony under Federal law for conduct involving health care fraud, and, on the basis of the conviction and other information, finds that Dr. Justice has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products.

As a result of the foregoing finding, Dr. Justice is debarred for 25 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see DATES) (see sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). Any person with an approved or pending drug product application who

knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Justice, in any capacity during Dr. Justice's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Justice provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Justice during his period of debarment (section 306(c)(1)(A) of the FD&C Act).

Any application by Dr. Justice for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2011-N-0860 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 22, 2012.

Armando Zamora,
Acting Director,
Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012-16600 Filed 07/06/2012 at 8:45 am; Publication Date: 07/09/2012]